

Cross-border healthcare in the European Union

the right to reimbursement under Directive 2011/24



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1 Introduction to the work

1.1 Presentation of the topic

Healthcare was for long not considered a matter to be dealt with by the European Union (EU). It was looked at as outside of the competence of the EU and the legal entitlements of the individual patient to access healthcare services, both inside and outside of its country of residence, was considered purely a matter of national law.

Healthcare services and systems are organized and financed differently between the EU Member States. Broadly, the systems can be classified as social insurance based Bismarck systems (with a further distinction between benefits in kind and restitution systems) and publicly funded Beveridge systems (also known as national health services funded centrally by taxation).¹ The various legal systems of the Member States have different rules on how expenses for healthcare obtained abroad are reimbursed and the EU has not been involved in regulating these payments.

The right to get healthcare in another EU Member State, and have the expenses covered by the home State, was first established by Regulation 1408/71 on the application of social security schemes to employed persons and their families moving within the Community (later replaced by Regulation 883/2004 on the coordination of social security systems). The Regulation was intended to guarantee workers and their family members the right to social security benefits regardless of their country of employment. This made it possible for people to use their right to free movement within the Union. Coordination of the various social security systems was therefore the main goal of the Regulation, as well as giving individuals certain restricted rights to reimbursement of foreign medical expenses.

¹ *Health Systems Governance in Europe: The Role of European Union Law and Policy*, Elias Mossialos ... [et al.]. Cambridge, (Cambridge University Press) 2010, p.12. For further reading about the different systems: Bismarck versus Beveridge: Social Insurance Systems in Europe, Center for Economic Studies Institute, report 4/2008. <http://www.cesifo-group.de> – last visited 15 November 2011

Today the situation is, however, very much different. The European Court of Justice (“Court of Justice” or “Court”) gave, in its famous rulings in the cases of *Kohll*² and *Decker*³ in 1998, some guidelines on how the EU Member States should deal with the issue of cross-border healthcare. In its rulings the Court used the Treaty rules on free movement and the creation of an internal market to extend the right of the individuals to seek healthcare services cross-borders and get the costs reimbursed by the home Member State. The Court stated that although national rules on social security were in line with the social security Regulation, the national rule could still constitute a restriction to the right to free movement. The jurisprudence of the Court on cross-border healthcare services has, over the years, gradually extended the rights of individuals to seek reimbursement for treatment in another Member State. This has consequently led to a need for the EU to adopt legislation to coordinate and clarify the patients’ rights.

The European Union adopted in March 2011 Directive 2011/24⁴ on the application of patients’ rights in cross border healthcare (the patients’ rights Directive) with the purpose of establishing a Community framework facilitating access to safe and high-quality cross-border healthcare. The Directive codifies the old case law from the Court of Justice on cross-border healthcare services, which should create accountability and transparency for patients who wish to seek healthcare cross borders. The main rule laid down in the Directive is that patients shall in principle be free to seek healthcare to another EU Member State, and get the costs reimbursed by the home State. The Directive allows the Member States to limit the application of the rule, e.g. by overriding reasons of general interest and by introducing a system of prior authorization. The Directive also includes new rules promoting cooperation and mutual assistance in healthcare between the Member States.

² Case C-158/96 *Kohll v Union des Caisses de Maladie* [1998] ECR I-1931

³ Case C-120/95 *Nicolas Decker v Caisse de maladie des employés privés* [1998] ECR I-1831

⁴ Directive 2011/24 of 9 March 2011 of the European Parliament and the Council on the application of patients’ rights in cross-border healthcare (*OJ L 88, 4 April 2011 p.45*)

1.2 The research question

Healthcare has traditionally been provided on a territorial basis, where patients contribute to a national system either through taxation or by paying premiums into an insurance scheme. In return the individuals receive relevant healthcare by a locally based healthcare provider.⁵ The European Union has, due to a need for legal clarity regarding the individual right to seek healthcare in another EU Member State, adopted a Directive on patients' rights in cross-border healthcare.

This dissertation will discuss the Court's rulings on cross-border healthcare that lead to the new Directive. It will discuss how the rules of the new Directive on cross-border healthcare will influence the rights of individuals to reimbursement for healthcare services obtained cross country, and the relationship between the new Directive and the Court's previous rulings. Hereunder it will be discussed whether the rules in Article 8 on prior authorization change the legal situation from how the Court previously interpreted it. Furthermore, the legal opportunity of the European Union to legislate the healthcare area and the relation between the new Directive and the existing social security coordination Regulation will be discussed.

1.3 Scope and limitations

In this dissertation the focus will primarily be on EU law and the Court interpretation of the law. However, references will be made to national rules where appropriate.

In the Court's judgments the Court has stated that the Treaty rules on free movement affect the right to seek healthcare services cross-borders. The Court has also ruled that other Treaty rules of economic nature can affect that right, such as the rules on competition, state aid and public procurement, but those rules mostly affect the national rules on healthcare. These areas will not be addressed in this dissertation.

⁵ Barnard, Catherine. *The Substantive law of the EU, the four freedoms*. 3rd edition. Oxford, (Oxford University Press) 2010, p.395

The service providers' right to establishment in another Member State according to Article 49 TFEU will not be discussed specifically.

1.4 Methodology and sources

For the writing of this dissertation information has been gathered from a variety of sources. These include academic literature, judgments, EU legislation and preparatory documents.

Directive 2011/24 on the patients' rights in cross-border healthcare has recently been adopted, and there is not much academic literature to find on the substance of the Directive. Preparatory documents for the Directive and previous judgments of the Court of Justice in the area of cross-border healthcare are, therefore, the main sources of reference for the Directive's interpretation.

Citations will generally be made to the Articles of the current Treaties and secondary legislation, older references will however be included where relevant.

The EU Treaties, the Treaty on European Union (TEU)⁶ and the Treaty on the Functioning of the European Union (TFEU)⁷ set out the organization and competence of the European Union. The main rules of relevance for this Dissertation are the rules of the TFEU. For practical purposes, when reference is made to "the Treaty" it is the TFEU that it is being referred to.

1.5 Structure

This dissertation is divided into 6 chapters. The first chapter is an introduction to the work, and includes introduction to the main topic, the research objectives and methodology. In chapter two the rules of the Treaties will be explored in order to establish whether the Union has competence to regulate in the area of healthcare. In that chapter the relevant rules of the social security Regulation will also be addressed. In the

⁶ Treaty on European Union (*OJ C 83 of 30 March 2010 p.13*)

⁷ Treaty on the Functioning of the European Union, signed in Lisbon (*OJ C 83 of 30 March 2010 p.47*)

third chapter important case law from the Court of Justice and the EFTA Court will be discussed. The arguments set out by the courts will be explored with the purpose of establishing how the rulings have extended the competence of the Union by referring to the internal market rules of the Treaty. The mentioned chapters are all necessary in order to contextualize the Directive on patients' rights in cross-border healthcare, as well as to understand the rules set out in the Directive. In chapter four Directive 2011/24 on patients' rights in cross-border healthcare is introduced and in the following chapter the main focus will be on Articles 7 and 8 of the Directive, i.e. the right to reimbursement of healthcare expenses obtained in another EU Member State, and the prerequisite of prior authorization. The last chapter will include the conclusion and concluding remarks.

2 The European Union and healthcare

The Treaty on European Union defines in its preamble and introductory section the aims, goals and values of the European Union and of the European Community. Article 3 of the Treaty sets out the tasks for the Union and explains the main purpose of the EU. Paragraph 3 of the Article concerns the creation of an area without internal frontiers:

The Union shall establish an internal market. It shall work for the sustainable development of Europe based on balanced economic growth and price stability, a highly competitive social market economy, aiming at full employment and social progress, and a high level of protection and improvement of the quality of the environment. It shall promote scientific and technological advance.
(...)

One of the main tasks of the Union shall, therefore, be the creation of an internal market. The internal market rules and the application of those rules on cross-border healthcare form the starting point of this overview of the legal tools that the Union has to regulate in the area of healthcare.

2.1 The competence of the European Union to act in the field of healthcare

The powers of the European Union to regulate certain areas of the Member State's internal law are governed by the Treaties. The EU institutions may not adopt any new law or policy that exceeds the powers given to them by the EU Member States. The power to regulate certain areas of the Member State's law is mainly in three ways as set out in Articles 3, 4 and 6 of the Treaty. Either the competence is primarily at EU level, where the EU alone is able to legislate and adopt binding acts. The Member States role is then limited to applying these acts, unless the Union authorizes them to adopt certain acts themselves. This exclusive competence is considered necessary in areas such as those affecting the customs union and the monetary policy. Oppositely, the competence can be primarily on the Member State level, where the Member States retain most of the

legislative power to adopt binding acts. Consequently, the EU has no legislative power in these fields and may not interfere in the exercise of these competences reserved for the Member States. The EU may only act in order to support, coordinate or complement the action of Member States. This shall apply in areas such as protection and improvement of public health and education. The third possibility is where the EU and the Member States share the competence, and are both authorized to adopt binding acts. The Member States may however only exercise their competence in so far as the EU has not exercised, or has decided not to exercise its own competence. This can be in areas such as those affecting the internal market, social policy and consumer protection.⁸

To find out at what level of governance the legislative competence is in the area of health and healthcare law, one has to examine the EU Treaties and the rules set out in them regarding this area of law. This exercise will also give an indication of how much economic and social integration there may be expected in the healthcare area. In the next subchapter the competence resulting from the Treaties and secondary legislation will be explored.

2.2 The Treaties

It has been much debated whether the European Union has competence to act in the area of healthcare. In the original EEC treaty that created the European Community, the Treaty of Rome of 1957, only limited reference was made to health. This was done by a reference either to “protection of health” or “public health”⁹, and prior to the Treaty of Maastricht¹⁰ the EU institutions had no clear competence in the field of health.¹¹

⁸ Division of competences within the European Union, accessible at: http://europa.eu/legislation_summaries/institutional_affairs/treaties/lisbon_treaty/ai0020_en.htm - last visited 22 October 2011

⁹ Reference was made to health in Articles 36, 48(3) and 56(1)

¹⁰ Treaty on European Union, signed in Maastricht (*OJ C 325 of 24 December 2002*, p.5)

¹¹ Hervey, Tamara K. and McHale, Jean V. *Health Law and the European Union*. Cambridge, (Cambridge University Press) 2004, p.72

Since then there have been several Treaty amendments and in the process the focus has moved towards creating an area of law where the competence to act is shared between the EU and the Member States.¹² The Lisbon Treaty of 2009 represents the final step in the process of integrating health services in the European Union. The Treaty amendments have also taken into consideration the Court interpretation of the fundamental principles of EU law and their interaction with healthcare services.¹³

As is stated in Article 4 of the TFEU, the competence in public health matters shall be shared between the EU and the Member States. It is then stated in Article 6 TFEU that the Union shall have competence to carry out actions to support, coordinate or supplement the actions of the Member States regarding the protection and improvement of human health. Article 3 TFEU, which refers to the areas where the Union has exclusive competence, does not include health.

In title XIV of the TFEU, Article 168 concerns public health. The Article mainly provides for cooperation between the Member States in the area of health, as well as stating that Union action shall complement the national policies. The first paragraph of the Article states that high level of health protection shall be ensured in all Union policies and action. The concluding paragraph states that Union action shall respect the responsibilities of the Member States for the definition of their health policy, and for the organization and delivery of health services and medical care. The Article also states that, included in the Member States responsibilities shall be the management of health services and medical care and the allocation of resources assigned to them. This concluding paragraph of Article 168 shows how the real responsibility of organizing and delivering healthcare lies with the Member States themselves, and that the competence of the Union is limited in that regard.

The internal market legal base is to be found in Article 114 TFEU. In Article 114(3) it is stated that, when measures adopted by the Union aim at establishing or ensuring the functioning of the internal market, they must guarantee a high level of protection of health.

¹² For detailed information about the Treaty amendments see Hervey, Tamara K., op. cit. n.11 p.72-81

¹³ *Health care and EU law*, Johan Willem van de Gronden ... [et al.]. The Hague, (T.M.C. Asser Press) 2011, p.22

As seen from the mentioned Articles of the Treaty it is clear that the European Union and the Member States shall share competence in the area of common safety concerns in public health matters. It is also clear that the Union shall have the competence to carry out actions to support, coordinate or supplement the actions of the Member States regarding the protection and improvement of human health. Following the TFEU the Member States, therefore, do not in any regard hold exclusive competence in the area of health.¹⁴

To summarize the competence gained from the Treaties, it appears that the line dividing the competence to regulate in the area of healthcare between the Member States and the EU is blurred. The competence conferred on the EU by the Treaties has, however, expanded over time and the Union has therefore gained increased powers to regulate in this area of law. Professor Wyatt¹⁵ has written that the Union competence to regulate medical services based on Article 114 will much depend on the specific subject matter under consideration. He considers that medical services are in principle open to regulation by harmonization measures adopted by the Union institutions under Article 114, but only up to the extent that medical services are considered services within the meaning of Article 56.

This area of law has over the years become of bigger interest to the EU. Consequently, the Member States have shown more interest in retaining their powers to control and regulate this area, as healthcare expenditure is a big proportion of the national budget.

2.2.1 National autonomy over the healthcare systems

It follows from Article 168(7), and has been confirmed in many rulings from the Court of Justice, that the EU shall respect the powers of the Member States to organize their social security systems, and the delivery of healthcare services and medical care.¹⁶

¹⁴ van de Gronden, Johan Willem ... [et al.] (2011) op. cit. n.13, p.23

¹⁵ *Social Welfare and EU Law*. Edited by Michael Dougan and Eleanor Spaventa, Hart Publishing, Oxford and Portland, Oregon (2005) p.142-143

¹⁶ Case C-238/82 *Duphar BV and others v The Netherlands State* [1984] ECR 523, para 16, Joined cases C-159&160/91 *Christian Poucet v Assurances Générales de France and Caisse Mutuelle Régionale du*

The Court of Justice has consistently stated in its rulings that where an area of law is not harmonized at EU level, it is for the Member State to determine its national rules. It has stated that it is, therefore, for the Member States to determine (i) the conditions concerning the right or duty to be insured with a social security scheme,¹⁷ (ii) which insurance schemes are provided and (iii) the conditions for entitlement to benefits¹⁸.

2.3 The social security coordination Regulation

The original right to receive healthcare in another Member State at the expense of the home State was set out in Regulation 1408/71¹⁹ on the application of social security schemes to employed persons and their families moving within the Community, and Regulation 574/72²⁰ implementing the former. The Regulations were replaced by the social security coordination Regulation 883/2004²¹ and the implementing Regulation 987/2009²², which entered into force in May 2010. The new legislative package has been referred to as “modernized coordination” of the social security systems in the EU.²³

Languedoc-Roussillon and Daniel Pistre v Caisse Autonome Nationale de Compensation de l' Assurance Vieillesse des Artisans [1993] ECR I-637, para 6, *Decker*, op. cit. n.3, para 21, *Kohll*, op. cit. n.2, para 17, Case C-157/99 *Geraets-Smits v Stichting Ziekenfonds VGZ and Peerboms v Stichting CZ Groep Zorgverzekeringen* [2001] ECR I-5473, para 44, Case C-372/04 *Yvonne Watts v. Bedford Primary Care Trust* [2006] ECR I-4325, para 92

¹⁷ Case 110/79 *Coonan v Insurance Officer* [1980] ECR 1445, para 12, *Kohll*, op. cit. n.2, para 18, *Decker*, op. cit. n.3, para 22, *Smits and Peerboms*, op. cit. n.16, para 45, Case C-56/01 *Patricia Inizan v Caisse primaire d'assurance maladie des Hauts-de-Seine* [2003] ECR I-12403, para 17, Case C-385/99 *Müller-Faure v Onderlinge Waarborgmaatschappij OZ Zorgverzekeringen UA and van Riet v Onderlinge Waarborgmaatschappij ZAO Zorgverzekeringen* [2003] ECR I-4509, para 100

¹⁸ Joined cases C-4&5/95 *Fritz Stöber and Jose Manuel Piosa Pereira v Bundesanstalt für Arbeit* [1997] ECR I-511, para 36, *Kohll*, op. cit. n.2, para 18, *Decker*, op. cit. n.3, para 22, *Watts*, op. cit. n.16, para 92

¹⁹ Regulation 1408/71 of the Council of 14 June 1971 on the application of social security schemes to employed persons, to self-employed persons and to members of their families moving within the Community (*OJ L 149 of 5 July 1971, p.2*)

²⁰ Regulation 574/72 of the Council of 21 March 1972 laying down the procedure for implementing Regulation 1408/71 (*OJ L 74 of 27 March 1972, p.1*)

²¹ Regulation 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems (*OJ L 166 of 30 April 2004, p.1*)

²² Regulation 987/2009 of the European Parliament and of the Council of 16 September 2009 laying down the implementing procedure for Regulation 883/2004 (*OJ L 284 of 30 October 2009, p.1*)

²³ *Cross-border health care in the European Union*. Edited by Matthias Wismar ... [et al]. World Health Organization on behalf of the European Observatory on Health Systems and Policies, 2011, p.6

In the EU, the various social security systems are coordinated by the Regulations but not harmonized. When Regulation 1408/71 was put in place, it was intended to establish entitlements to social security benefits for citizens moving to another Member State. The social security Regulation is, on the other hand, considered to be more of a “safety net”²⁴ as it guarantees patients’ minimum rights to access healthcare in another Member State if they cannot access the necessary care in their home State.

Regulation 1408/71 was amended regularly, partly in order to take into consideration the Court jurisprudence on healthcare services. The difference between the old and the current social security Regulations is not significant for the purposes of this dissertation. The main difference is that the administrative processes have been improved in order to make the individual rights following the Regulation more effective and user friendly for the citizens.²⁵

The current social security Regulation has a broader personal scope than its predecessor. The Regulation applies both to nationals of a Member State and stateless persons and refugees residing in the Member State, who are or have been subject to the legislation of one or more Member States, as well as to the members of their families and to their survivors. Regulation 1408/71 was originally limited to employed persons but the scope was later broadened so that it also applied to self-employed persons, civil servants and students.

The various categories of benefits covered by the coordination Regulation are defined in Article 8. When a person relies on the Regulation for entitlement to benefits, the mechanism of the Regulation seeks to answer three key questions that explain the individual’s social security coverage, (i) in what Member State and under which conditions is an entitlement to healthcare benefits in kind opened (ii) which legislation determines the scope of the entitlement to benefits and (iii) what Member State will have to cover the costs?²⁶

²⁴ European Commission communication, A Community framework on the application of patients’ rights in cross-border healthcare, *COM (2008) 415 final of 2 July 2008*, p.5

²⁵ Matthias Wismar ... [et al.], op. cit. n.23, p.6

²⁶ Elias Mossialos ... [et al.], op. cit. n.1, p.514

Chapter 1 of Title III of Regulation 883/2004 concerns sickness benefits. A person seeking healthcare in another Member State can according to that chapter of the Regulation be entitled to benefits in kind. Benefits can generally be provided by two means; benefits in kind or benefits in cash. Sickness benefits in cash are intended to be an income replacement, while sickness benefits in kind are linked to personal services (e.g. medical treatment) and remedies and aids (e.g. crutches or wheelchairs).²⁷

Of relevance to the topic of this Dissertation are Articles 19 and 20 of the Regulation. Article 19 concerns treatment that becomes necessary when the patient is on a short term stay in another Member State, and Article 20 deals with the rights of patients that travel to another member State with the purpose of seeking medical treatment.

2.3.1 Necessary treatment during a short term stay in another Member State

In the situation when a persons' medical condition requires benefits in kind which become necessary during a temporary stay in another Member State, the necessary treatment is guaranteed by Article 19 of the Regulation. In such circumstances, a European Health Insurance Card (EHIC) issued by the competent institution of the home State, indicating the right to benefits in kind, shall be presented to the healthcare provider in the EU Member State where emergency treatment is needed.²⁸

Given that conditions set out in Article 19 are fulfilled, the patient is entitled to benefits in kind that are provided on behalf of the home State. The benefits are provided by the institution in the place of stay and in accordance with the legislation which it administers as though the person was insured under the system of that Member State.

Under these circumstances no authorization for treatment is required by the home State. The patient pays for the healthcare as if he was insured in that Member State where the

²⁷ Zaglmayer, Bernhard and Einarsson, Olafur, *Access to and Reimbursement of Health Care in the European Economic Area*, (2009) Tidsskrift i Erstatningsrett – nr. 3 2009/årgang 6, chapter 2.2

²⁸ Article 25 A (1) of Regulation 987/2009 laying down the implementing procedure for Regulation 883/2004 (*OJ L 284 of 30 October 2009, p. 1*). If the insured person has no such document the institution of the place of stay can, if needed, contact the competent institution of the home State to obtain confirmation of insurance.

treatment is received. The competent authorities of the affected Member States may then create a system of reimbursement between them according to Article 35 of the Regulation.²⁹

2.3.2 Planned treatment in another Member State

Article 20 of the Regulation sets out in its first paragraph, that an insured person travelling to another Member State with the purpose of receiving benefits in kind during the stay shall seek prior authorization from the competent institution in the home State. Following the Article, prior authorization is, therefore, a prerequisite for getting the costs for treatment abroad reimbursed.

Paragraph 2 of the same Article concerns the rights of a person who has received authorization to seek healthcare in another Member State. The person shall receive the benefits in kind that are provided by the institution in the place where the treatment is sought and in accordance with the legislation it applies, as if the patient was insured under that legislation. The benefits are provided by that State, on behalf of the home State. Where the authorization has been granted, the costs for the treatment are mostly paid directly by the institution in the home State where the person is insured, to the foreign healthcare provider.

The home State has a duty to grant the prior authorization where the treatment needed (i) is amongst the benefits provided for in the legislation of the home Member State and (ii) where the necessary treatment cannot be given at home within a medically justifiable time limit. When evaluating the need for treatment abroad the patients' current state of health and the probable course of the illness shall be taken into account. The Regulation follows the principle repeatedly confirmed by the Court of Justice that Community law does not detract from the power of the Member States to organize their social security systems.³⁰ The Regulation is therefore not intended to affect the core of

²⁹ Article 25 B (4) and (5) of Regulation 987/2009 op. cit. n.28, explains a different procedure of reimbursement of medical expenses obtained abroad in the situation where the patient has actually borne the cost of all, or part, of the treatment received abroad

³⁰ Op. cit. n.16

the national rules, *inter alia*, on what healthcare it makes available to its citizens. It does, however, establish some degree of coordination between the various social security systems and secures minimal social and healthcare benefits for all. The medically justifiable time limit has been interpreted by the Court as situations where a patient is facing “undue delay” for necessary treatment at home. In these circumstances the home State is in breach of the Regulation by refusing authorization.

When authorization has been given according to Articles 19 and 20 of the Regulation, the competent institution of the home Member State has, according to Article 35, the duty to reimburse fully the costs for the treatment to the competent institution in the State of treatment. The implementing Regulation 987/2009 sets out in Article 62 the principles for reimbursement of costs between the relevant institutions.

In the cases of *Kohll* and *Decker*, Regulation 1408/71 was challenged based on the Treaty rules on free movement. The relevant cases concerning the internal market rules and how they interact with the rules of the social security coordination Regulations will be discussed in the next chapter.

3 The European Union market rules

The starting point of the influence of EU law on health and healthcare was with the application of the internal market rules on this sector. EU market rules, e.g. the free movement rules, competition law and other EU law of economic nature are rules that can interfere with the national organization of healthcare. The rules can produce disruptive effects and challenge the national solidarity, that healthcare services are based on.³¹

3.1 Interaction with the internal market

The internal market of the European Union is based on four freedoms: free movement of goods, persons, services and capital. In the seminal rulings in the cases of *Kohll* and *Decker* the Court applied the Treaty provisions on free movement, and considered healthcare services to be services of economic nature. The economic nature of the service is the only determining criterion to confirm if the service comes under the scope of the Treaty provisions on free movement of services.³² By referring to the free movement provisions in the Treaty [EC Treaty] the Court gave signals indicating that national healthcare and especially the Member States organization of healthcare (such as planning), can be affected by the application of EU law.³³

The Court could have rejected the application of Articles 56 and 57 TFEU on national healthcare by arguing that healthcare did constitute an economic activity. The Court however stated that the Treaty rules on the internal market applied to healthcare services and that the Member States could use the public interest requirements to reconcile restrictions to the principle of free movement.³⁴

³¹ van de Gronden, Johan Willem ... [et al.] (2011) op. cit. n.13, p.3

³² Elias Mossialos ... [et al.], op. cit. n.1, p.465

³³ van de Gronden, Johan Willem ... [et al.] (2011) op. cit. n.13, p.2

³⁴ Barnard, Catherine, op. cit. n.5, p.396

Public education is something that might be considered by many to fall in the same category as healthcare services. The Court however excluded education services from the scope of the free movement of services in the cases of *Humbel*³⁵ and *Wirth*³⁶, as the public education system did not constitute services of economic character. In these rulings the Court mainly referred to the fact that (i) in services, the price is normally agreed upon between the provider and the recipient of the service, and the Court considered that characteristic absent when services are provided under the national education system, (ii) the State, when establishing and maintaining the national education system, is not seeking to engage in gainful activity, but is fulfilling its duties towards its own population in the social, cultural and educational fields, and (iii) the education system is generally financed from the public purse.³⁷

3.1.1 Free movement of services

When considering the legal framework for cross border healthcare Articles 56 and 57 TFEU on the free movement of services are of relevance. Article 56 prohibits restrictions on the freedom to provide services within the Union, while Article 57 explains what services come within the scope of the Treaty. Services are economic activities, and shall particularly include activities of industrial or commercial character, activities of craftsmen or of the professions, normally provided for remuneration, in so far as they are not governed by the provisions relating to freedom of movement for goods, capital or persons. To fall within the Treaty, the service must therefore be provided for remuneration, i.e. there needs to be an economic link between the service provider and recipient.³⁸

In its rulings the Court has found that the Treaty rules on services are relevant when EU nationals travel to another Member State to receive medical treatment, because medical services constitute ‘services’ within the meaning of Article 57 TFEU. This was first

³⁵ Case 263/86 *Belgian State v René Humbel and Marie-Thérèse Edel* [1988] ECR 5365

³⁶ Case C-109/92 *Stephan Max Wirth v Landeshauptstadt Hannover* [1993] ECR I-6447

³⁷ *Humbel*, op. cit. n.35, para 17-19, *Wirth*, op. cit. n.36, para 15

³⁸ See for example Barnard, Catherine, op. cit. n.5, p.361-363, where reference is made to several cases from the Court explaining the economic link

stated by the Court in the breakthrough case of *Luisi and Carbone*³⁹ of 1984, where the Court ruled that it is not only the providers of services that are within the scope of protection but also the recipients. The Court did, however, say that the freedom to provide and receive services may be restricted, and explained that the Member States can justify such restrictions on grounds of public policy, public security and public health.⁴⁰

An important ruling was given in the previously mentioned case of *Kohll*.⁴¹ Mr Kohll, a Luxembourg national, brought his daughter to a dentist established in Germany without seeking prior authorization as required by national law when treatment was sought abroad. When the same treatment was acquired domestically no prior authorization was required. Mr Kohll was refused authorization and the case was brought to the Court of Justice, where Mr Kohll asserted in particular that the Luxembourg authorities had only considered whether the national rules were consistent with the social security Regulation [1408/71] but not whether they were consistent with Articles 56 and 57 [59 and 60] of the Treaty.

The Court, with reference to Mr Kohll's arguments, found that the fact that the national rules at issue fall within the sphere of social security cannot exclude the application of the Treaty rules on free movement of services.⁴² The Court furthermore found that the national rule on prior authorization would make it more difficult to approach a service provider established in another Member State, than one providing the service within the same Member State. The national rule would therefore deter insured persons from seeking medical services in another Member State and would, consequently, constitute a barrier to the freedom to provide services.⁴³ The Court then went on to examine whether the national measure could be objectively justified.

The Luxembourg authorities argued that requiring prior authorization was an effective way of preventing the risk of upsetting the financial balance of the social security

³⁹ Joined Cases C-286/82 and C-26/83 83 *Graziana Luisi and Giuseppe Carbone v. Ministero del Tesoro* [1984] ECR 377

⁴⁰ See that Article 62 TFEU refers to Article 52(1) TFEU

⁴¹ *Kohll*, op. cit. n.2

⁴² *Ibid*, para 21

⁴³ *Ibid*, para 34-35

scheme. They furthermore claimed that the national rule of prior authorization aimed at ensuring a balanced medical and hospital service available to all insured persons, which constituted an overriding reason capable of justifying restrictions on the freedom to provide services. The Court considered this argument and found that as Mr Kohll was asking for reimbursement at the same rate as applied in Luxembourg there was no significant effect on the financing of the social security system.⁴⁴

The Luxembourg authorities also argued that the rule could be justified on public health grounds in order to ensure the quality of medical services. The Court, however, found that since the conditions for taking up and exercising professional activities of health professionals had been subject to EU harmonization directives, the quality of the service was guaranteed.⁴⁵

On these grounds the Court found that the national rule requiring prior authorization was in breach of the Treaty rules on free movement of services.

This ruling led to a situation where the coordination Regulation (art. 22(2) of Reg. 1408/71, now art. 20 of Reg. 883/2004), requiring prior authorization for reimbursement, and the Treaty rules now were in conflict with each other. The Court continued and explained that although a national measure may be consistent with secondary legislation from the EU, it may still be incompatible with the Treaty. The Treaty is a higher norm than the secondary legislation, and as confirmed in this case, Articles 56-57 of the Treaty are able to reshape and override the social security coordination Regulation, and subsequently other secondary legislation from the EU.

The case of *Decker*⁴⁶ also concerned Luxembourg national rules, where Mr Decker asked for reimbursement for spectacles bought in Belgium. The Court used the same

⁴⁴ Ibid, para 37-42

⁴⁵ *Kohll*, op. cit. n.2, para 47. See Council Directive 78/686 of 25 July 1978 concerning the mutual recognition of diplomas, certificates and other evidence of the formal qualifications of practitioners of dentistry, including measures to facilitate the effective exercise of the right of establishment and freedom to provide services (*OJ L 233 of 24 august 1978 p.1*), Council Directive 78/687 of 25 July 1978 concerning the coordination of provisions laid down by law, regulation or administrative action in respect of the activities of dental practitioners (*OJ L 233 of 24 august 1978 p.10*) and Council Directive 93/16 of 5 April 1993 to facilitate the free movement of doctors and the mutual recognition of their diplomas, certificates and other evidence of formal qualifications (*OJ L 165 of 7 July 1993 p.1*)

⁴⁶ *Decker*, op. cit. n.3,

arguments as in the *Kohll* case, but this time the Court found that the national measure was contrary to the Treaty rules on the free movement of goods, Articles 34 and 36 [30 and 36].

The cases of *Kohll* and *Decker* show that making the reimbursement of healthcare expenses obtained in another EU Member State completely dependent on prior authorization is a breach of the Treaty rules on free movement. These rulings of the Court introduced an alternative procedure for the reimbursement of expenses for healthcare received in another Member State. The original route, created by the social security Regulation, provides for full reimbursement of the costs, whereas the Treaty route, based on the free movement of services, only provides for reimbursement up to the level of what the healthcare would have cost had it been provided at home.

The mentioned cases of *Kohll* and *Decker* created strong reactions by the national authorities and others involved in organizing, financing and providing healthcare.⁴⁷ The rulings suggested that in respect of healthcare provided outside of a hospital, the requirement of prior authorization could not be justified. This would seemingly entitle patients to demand treatment in other Member States and be reimbursed for the costs of the treatment by the competent authority in the home State. Following the rulings this seemed to be a judicially enforceable right. The cases, however, left some questions unanswered, e.g. whether the same rules applied to hospital treatment, and whether the principles laid down in the cases applied to a system based on benefits in kind rather than on reimbursement.⁴⁸ These questions were considered by the Court in its later rulings.

In the Court ruling in *Vanbraekel*⁴⁹ the importance of what the Treaty provisions could achieve was seen again. The case concerned a woman insured in Belgium, who had received hospital treatment in France and was wrongfully denied prior authorization. The authorization was later approved, and the question raised for the Court was whether

⁴⁷ Matthias Wismar ... [et al.], op. cit. n.23, p.26

⁴⁸ Hervey, Tamara K., op. cit. n.11, p.127

⁴⁹ Case C-368/98 *Abdon Vanbraekel and Others v Alliance nationale des mutualités chrétiennes (ANMC)* [2001] ECR I-5363

the reimbursement should be calculated according to the tariffs in the host State, where she was treated, or of the State of residence, where she was insured.

The Court looked at Article 20 of the social security coordination Regulation [22(1)(c) of Regulation 1408/71] and Article 56 [59] of the Treaty. The Regulation provided that when an insured person has been authorized by the home State to seek treatment in another member State, the institution in the place where the treatment is given should provide the person benefits in kind, in accordance with its rules as if he the person was insured in that State. This should be provided on behalf of the competent institution of the home State and only the length of the period during which benefits are provided remains to be governed by the legislation of the home State.

The Court stated that when such an authorization had been wrongfully refused, and later found that the refusal had been unfounded, the person is entitled to be reimbursed directly by the competent institution of the home State. The amount to be reimbursed should be equivalent to that which had been paid had the authorization been properly granted in the first place.⁵⁰ In this case it meant reimbursement under the French rate, which was lower than the Belgian rate that would have applied had the treatment been provided at home.

The Court applied Article 56 [59] of the Treaty to fill the gap and started by stating that it was settled case law that medical activities fall within the scope of the Treaty rules on free movement of services. The Court continued and found that there was no need to distinguish between care provided in a hospital and care provided outside such environment.⁵¹ The Court then noted that if patients had a lower level of cover when they receive hospital treatment in another Member State than they would in the Member State where they are insured, it could have the effect of preventing persons from applying to providers of medical services established in other Member States. That would constitute a barrier to the freedom to provide services, both for insured persons and for service providers.⁵²

⁵⁰ *Vanbraekel*, op. cit. n.49, para 53

⁵¹ *Ibid*, para 41

⁵² *Ibid*, para 45

The Court found, that where the amount of reimbursement is less if calculated according to the scheme of the Member State of treatment than if calculated according to the scheme of the home Member State, additional reimbursement covering the difference must be granted.⁵³ Article 56 [59] therefore required reimbursement at the rate of the more beneficial State.

In the *Smits-Peeboms*⁵⁴ judgment the requirement of prior authorization to seek hospital service in another Member State was challenged under the Treaty rules on services. The Court confirmed (as it did in *Vanbraekel* that was published at the same day) that there was no need to distinguish between care provided within a hospital and care provided outside hospital.⁵⁵

The Court furthermore found that Articles 56 and 57 TFEU [59 and 60] did not preclude legislation that makes the reimbursement of costs of treatment in another Member State subject to prior authorization. The Court explained that such authorization could be made subject to the conditions that; the treatment must be regarded as “normal in the professional circles concerned” and the persons’ medical condition must require the treatment. The Court however found that this only applied so far as the requirement that the treatment must be regarded as “normal”, cannot be refused on that ground where it appears that the treatment concerned is sufficiently tried and tested by international medical science, and it can only be refused on the ground of lack of medical necessity if the same or equally effective treatment is available at home.⁵⁶

The Court therefore approved the refusal to provide prior authorization when the treatment sought is experimental or not scientifically proved, and when the same or equally effective treatment can be provided by a nationally based provider.

⁵³ Ibid, para 53

⁵⁴ *Smits and Peeboms*, op. cit. n.16

⁵⁵ Ibid, para 53

⁵⁶ Ibid, para 103

Along the same line are the joined cases of *Rindal* and *Slinning*⁵⁷ from the EFTA Court.⁵⁸ The cases both concerned Norwegian citizens seeking treatment abroad, requesting reimbursement from their national authorities. The EFTA Court considered it compatible with the rules of the EEA Agreement to refuse to cover expenses for medical treatment abroad “which according to international medicine must be considered experimental or test treatment when there is no entitlement to such treatment in the home State”.⁵⁹

In the case of *Müller-Faure and van Riet*,⁶⁰ the Court confirmed its previous ruling in the case of *Smits and Peerboms*, that hospital treatment falls within the rules in Articles 56 and 57 [59 and 60].⁶¹ The Court also found that the requirement of prior authorization constitutes a barrier to the freedom to provide services, both for the insured person and the service provider. The Court ruled that the Treaty rules must be interpreted as not precluding legislation of a Member State which (i) makes the assumption of the costs of care provided in a hospital in another Member State by a healthcare provider that the insurance fund has not concluded an agreement, conditional upon prior authorization by the fund and (ii) makes the grant of the authorization subject to the condition that the treatment is necessary for the insured persons health.⁶² However, authorization may be turned down if treatment which is the same or equally effective for the patient can be obtained without undue delay in an establishment which has concluded an agreement with the fund.⁶³ This was later also confirmed in the Court ruling in the case of *Inizan*⁶⁴.

⁵⁷ EFTA Court joined cases 11/07 and 1/08 *Olga Rindal and Therese Slinning v the Norwegian State* [2008] Ct. Rep. 320.

⁵⁸ The EFTA Court has jurisdiction with regard to EFTA States which are parties to the EEA Agreement (at present Iceland, Liechtenstein and Norway). The aim of the EEA Agreement is to guarantee the free movement of persons, goods, services and capital; to provide equal conditions of competition and to abolish discrimination on grounds of nationality in all 30 EEA States, the 27 EU States and 3 of the EFTA States

⁵⁹ *Rindal and Slinning*, op. cit. n.57, para 61

⁶⁰ *Müller-Fauré and Van Riet*, op. cit. n.17

⁶¹ *Ibid*, para 42

⁶² *Ibid*, para 109

⁶³ *Ibid*, para 109

⁶⁴ *Inizan*, op. cit. n.17

In the case of the 72 year old *Yvonne Watts*⁶⁵ the requirement of prior authorization could not be justified by the UK authorities. Ms Watt was diagnosed with osteoarthritis and was facing a one year wait for a hip replacement at her local hospital. Despite being refused to seek treatment abroad she travelled to France to have the operation done. The Court confirmed that patients facing “undue delay” at home, defined by their clinical condition rather than potentially arbitrary targets, may travel to another Member State for treatment and expect to receive reimbursement for the costs of treatment because of the undue delay.

The case *Commission v France*⁶⁶ concerned French rules that required anyone going abroad for diagnosis or treatment that needed “major medical equipment” to seek prior authorization if they were to be reimbursed. Here the Court confirmed that the requirement of prior authorization for treatment given outside of a hospital could be justified by the need to protect the financing of the health insurance system and to ensure proper planning of such equipment. It also noted that the prior authorization requirement was considered necessary in order to ensure a rationalized, stable, balanced and accessible supply of up to date treatment throughout the national territory and to avoid, so far as possible, any waste of financial, technical and human resources.⁶⁷ The Court referred to this ruling in the case *Commission v Portugal*⁶⁸ decided on 27 October 2011 which is the latest healthcare case of relevance to this dissertation. The Court stated that a Portuguese rule restricting reimbursement of non-hospital care that requires the use of major and costly equipment could be justified.

3.2 Summary of the case law – what does it tell us?

To conclude this overview of the relevant case law from the Court of Justice and the EFTA Court in the area of cross-border healthcare, it is clear that many questions still need to be answered or have unclear answers. Uncertainty about the entitlements to

⁶⁵ *Watts*, op. cit. n.16

⁶⁶ Case C-512/08 *European Commission v French Republic* [2010] ECR I-1297

⁶⁷ *Ibid*, para 26-43

⁶⁸ Case C-255/09 *Commission of the European Communities v Portuguese Republic* [2011] ECR I- Has not been published

reimbursement for cross-border healthcare can lead to reluctance by patients to seek healthcare abroad. This uncertainty can also create problems for the national authorities when organizing their healthcare systems.

In the mentioned cases the national organization of healthcare and the social security coverage is not an issue, as this is to be determined by the Member States themselves.⁶⁹ Individuals are in principle free to travel abroad and to seek medical care from whatever provider they choose. However, the case law tells us that this principle in practice is limited either to the ability of the patient to pay for the care, or by national and/or EU legislation that create conditions where patients are entitled to reimbursement of the expenses.

The Court has made clear that all medical services, whether provided inside a hospital or outside of a hospital environment, constitutes services within the meaning of Article 56 TFEU and do therefore fall within the scope of the Treaty.⁷⁰ However, in the judgments, the Court has made a distinction between treatment provided in or outside of hospital and found that hospital treatment may be subject to prior authorization.

The Court has found that the requirement of prior authorization, that is always required as a condition for reimbursement under the text of the social security Regulation, is *per se* a barrier to the freedom to provide services. This applies both to the freedom of the insured person and the service provider, as the national measure deters insured persons from approaching providers established in another Member State.⁷¹ The prior authorization requirement is considered to be justified based on reasons such as to safeguard the financial balance of the national social security system and planning in the hospital sector.

According to the case law, the Member States are allowed to maintain barriers to the free movement of services provided that they are justified in the public interest. The

⁶⁹ *Duphar*, op. cit. n.16, para 16, *Poucet and Pistre*, op. cit. n.16, para 6, *Decker*, op. cit. n.3, para 21, *Kohll*, op. cit. n.2, para 17, *Smits and Peerboms*, op. cit. n.16, para 44, *Watts*, op. cit. n.16, para 92

⁷⁰ This was first confirmed *Luisi and Carbone*, op. cit. n.39 and *Kohll*, op. cit. n.2 and later with hospital treatment in *Vanbraekel*, op. cit. n.49, para 41, *Smits and Peerboms*, op. cit. n.16, para 53, *Müller-Fauré and Van Riet*, op. cit. n.17, para 38

⁷¹ *Kohll*, op. cit. n.2, para 35, *Smits and Peerboms*, op. cit. n.16, para 61-69, *Müller-Fauré and Van Riet*, op. cit. n.17, para 44

Member States must prove that the measure is objectively necessary for ensuring the attainment of a public interest objective (necessity test), and that it does not exceed what is necessary to attain the objective, or that the same result can be achieved by a less restrictive rule (proportionality test) as well as the measure shall be applied in a non-discriminatory manner.⁷²

Prior authorization can be refused when the treatment sought is regarded as experimental or not scientifically proved, or when equally effective treatment can be provided by a nationally based provider within a medically justifiable time limit.⁷³ The Court has also accepted the legality of national rules requiring patients going abroad for diagnosis or treatment that needs “major medical equipment” to seek prior authorization.⁷⁴ The Court has also stated that the Member States cannot purely rely on the presence of waiting lists as part of a complex planning as an excuse to refuse to deny prior authorization.⁷⁵

The concept of “undue delay” has been a critical element of many cases before the Court. The Court confirmed in *Watts* that patients facing “undue delay” for treatment at home may access the same or equivalent services in other EU Member States and expect to receive reimbursement for the costs of treatment because of the undue delay.

The Court has developed a parallel regime for patient mobility to the pre-existing system in the social security coordination Regulation. The case law based system of reimbursement is based on Article 56 of the Treaty. When the patient relies on Article 56 TFEU, the reimbursement is made up to the level that the healthcare would have cost had it been provided at home. The social security coordination Regulation gives right to reimbursement at the rate of the State of treatment, which generally guarantees full reimbursement.⁷⁶

Under the Court case law on Article 56 and 57 it is the patient that bears the risk of the healthcare in the Member State of treatment costing more than it does in the home

⁷² *Müller-Fauré and Van Riet*, op. cit. n.17, para 68, *Smits and Peerboms*, op. cit. n.16, para 75

⁷³ *Smits and Peerboms*, op. cit. n.16, *Rindal and Slinning*, op. cit. n.57

⁷⁴ *Commission v France*, op. cit. n.66, *Commission v Portugal*, op. cit. n.68

⁷⁵ *Müller-Fauré and Van Riet*, op. cit. n.17, para 92

⁷⁶ Where reimbursement under the social security Regulation is lower, the difference may be claimed based on Article 56 TFEU, see *Vanbraekel*, op. cit. n.49,

State. If prior authorization is provided under the social security coordination Regulation, it is the public funds that bear the risk.

The Directive on services in the internal market is linked to the Courts progressive interpretation of the application of the Treaty rules on the free movement of healthcare services. In the initial proposal for a Directive the Commission attempted to clarify the individual rights to seek healthcare cross borders.

3.3 The services Directive

When the proposal for a Directive covering services in the internal market was launched⁷⁷ it included provisions on medical services in Article 23. The objective of this was to increase legal certainty in the area of cross-border healthcare. The provision was limited, but intended to codify the Court case law on healthcare services and was based on a distinction between hospital and non-hospital care.

The European Parliament and the Council voted for taking health services out of the Directive. In their opinion, the proposal did not take the specific nature of health services sufficiently into account, especially regarding the technical complexities, and the fact that this area is sensitive for the public opinion, and mostly founded by public funds. The Commission subsequently announced that a separate and more adapted initiative in the area of healthcare services was to be presented.⁷⁸

⁷⁷ Directive 2006/123 of the European Parliament and of the Council of 12 December 2006 on services in the internal market (*OJ L 376, 27 December 2006, p.36*). The initial proposal: *COM (2004) 2 final of 5 March 2004*

⁷⁸ Commission Communication, Proposal for a Directive of the European Parliament and the Council on the application of patients' rights in cross-border healthcare presented by the Commission, *COM (2008) 414 final of 2 July 2008, p.2*

4 Directive 2011/24 on the application of patients' rights in cross- border healthcare

Due to all the legal uncertainties surrounding cross-border healthcare services created by the Court rulings, it was clear for all parties involved that there was a need for clarification from the EU regarding the patients' rights. Already in 2003 the Commission was invited by the Health Ministers and other stakeholders to discuss how the legal certainty in cross-border healthcare could be improved.⁷⁹ After the Parliament and the Council in 2006 had voted healthcare services out from the scope of the services Directive it became clear that a measure, specifically addressing cross-border healthcare, was needed.

All EU institutions were involved in the preparation of the new legal framework, which was based on several external surveys, analyses and studies. In June 2006 the Council adopted a Conclusion on Common values and principles in European Union Health Systems⁸⁰ and stated that such a Conclusion would be of particular value for the new legislation. The Parliament made its contributions by writing various reports. Other stakeholders were also actively involved in the Commission activities regarding patient mobility and healthcare.⁸¹ In September 2006, the Commission formally launched a consultation with the relevant stakeholders involved in the health services sector, and invited them to contribute to a consultation process regarding Community action in healthcare services.⁸² The Commission received 280 responses from various groups, including health professional organizations, healthcare providers, governments and insurers. These comments were taken into account when preparing the legislative

⁷⁹ Commission proposal, op. cit. n.78, p.2

⁸⁰ Council Conclusions on Common values and principles in European Union Health Systems, (OJ 146 of 22 June 2006, p.1)

⁸¹ Commission proposal, op. cit. n.78, p.2

⁸² Communication from the Commission, Consultation regarding Community action on health services, SEC (2006) 1195/4, of 26 September 2006

proposal.⁸³ It was expected that the Commission would introduce the new legislative proposal by the end of 2007. However, the process got delayed due to many factors such as internal differences within the College of Commissioners, political difficulties and fear that the legislative proposal would be rejected, as happened in the prior attempt to regulate healthcare services by addressing the issue in the services Directive.⁸⁴

The conclusion of the work was the adoption of a Directive and the Commission finally published a proposal for a Directive on the application of patients' rights in cross-border healthcare in July 2008. The proposal's aim was to establish a general framework for provision of safe, high quality and efficient cross-border healthcare in the European Union. By that, also to ensure free movement of health services and a high level of health protection, while fully respecting the responsibilities of the Member States for the organization and delivery of health services and medical care.⁸⁵ The Commission published an Impact assessment⁸⁶ along with the proposal that it had used to choose between different policy options. In the assessment the Commission stated that cross-border healthcare was estimated to represent around 1% of the public expenditure on healthcare which is €10 billion per year.⁸⁷ The Commission has forecasted that under the rules of the Directive that cost increase a year will only be € 30 million.⁸⁸

The process of adopting the Directive was long and complex, not least due to complications in reaching a common consensus between the Parliament and the Council of Ministers. In April 2009 the Parliament voted in favor of the proposal after making several amendments to the text.⁸⁹ The adoption process was even more complicated in the Council, mainly caused by three points of contention. The most debated points were firstly, the legal base of the Directive and the principles of proportionality and

⁸³ Commission proposal, op. cit. n.78, p.3

⁸⁴ EurActiv, *Confusion surrounds EU's health services directive*, 28 January 2008

⁸⁵ Commission proposal, op. cit. n.78, p. 6

⁸⁶ Commission staff working document of 2 July 2008, accompanying document to the proposal for a Directive on patients' rights in cross-border healthcare: Impact assessment *SEC (2008) 2163*

⁸⁷ Ibid p.9

⁸⁸ Ibid p.63. These costs are estimated if policy options 3A or 4 are taken

⁸⁹ European Parliament Report on the proposal for a Directive of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare, *A6-233/2009 of 3 April 2009*

subsidiarity,⁹⁰ and secondly whether long-term care should be within the scope of the Directive and thirdly under which situations the Member States could refuse to provide prior authorization to seek hospital care abroad.⁹¹

In March 2011 the legislative act was adopted by the European Parliament and became law on 4 April 2011 when it was listed in the Official Journal of the European Union. The EU Member States are required to adopt the necessary laws, regulations and administrative provisions by 25 October 2013.⁹²

The Directive on patients' rights in cross-border healthcare was introduced in the context of the Commission renewed social agenda in 21st century Europe.⁹³ The renewed social agenda and the ideas presented along with it were intended to complement the Lisbon Treaty from a social perspective.

4.1 Legal basis and scope

In the initial proposal for a Directive the Commission states that it considers the Member States not able to sufficiently achieve the objectives of the proposal on their own. The Commission therefore considers, that by reason of the scale of action, the objectives will be better achieved at Community level, and that the principle of subsidiary and proportionality as set out in Article 5 of the Treaty on the European Union are complied with.⁹⁴

⁹⁰ The principles of subsidiarity and proportionality are one of the general principles of European Union law and govern the exercise of the competence of the EU. When the EU is dealing with matters where it does not have exclusive competence, the principle of subsidiarity seek to protect the capacity of the Member States to take decisions and action. It also authorizes the Union to intervene when the objectives of the action cannot satisfactorily be achieved by the Member States themselves due to the scale and effects of the proposed action. The purpose of including it in the European Treaties is also to ensure that the powers are exercised as close to the citizen as possible and that involvement is limited to what is necessary to achieve the objectives of the Treaties. The application of the principles of subsidiarity and proportionality is set out in Protocol 2, (*OJ C 310 of 16 December 2004, p.207*)

⁹¹ See overview of these discussions in: van de Gronden, Johan Willem ... [et al.] (2011) op. cit. n.13, p.118-125

⁹² See Article 21 of Directive 2011/24 on transposition

⁹³ Commission Communication of 2 July 2008 on the Renewed social agenda: Opportunities, access and solidarity in 21st century Europe, *COM (2008) 412 final of 2 July 2008*, p.11

⁹⁴ Commission proposal, op. cit. n.78, p.9. See also recital 64 in the preamble to the Directive

The Directive has its legal base in Articles 114 and 168 TFEU. As explained in chapter 2.2, Article 114 allows the Union to take action to set out harmonization measures that have as their objective the establishment and functioning of the internal market.

Paragraph 3 of the Article then requires those measures to guarantee a high level of human health protection, taking into account in particular any new developments based on scientific facts. Article 168 allows the EU to act in order to complement the national policies and encourage cooperation between the Member States. At the same time the EU shall respect the responsibilities of the Member States to define, organize and deliver health services and medical care.

The initial proposal for a Directive was only based on Article 114, whereas the Commission stated that it considered the proposal at the same time fully in line with the requirements set out in Article 168.⁹⁵ Having a double legal base, both of the internal market and public health, was one of the discussion points both in the Council and the Parliament. The main point of disagreement was that if the Directive would only be based on Article 114, the free movement of healthcare services could be seen too much only as an economic right, which could cause healthcare service providers to focus too much on the customers' buying power, rather than the patients' medical need. Different interest groups also had concerns that the social nature of healthcare and the idea of healthcare as a service in the general interest would be lost if the proposal would only be put forward in the context of internal market harmonizing measures, as these measures are linked to the exercise of economic rights.⁹⁶ The Council and the Parliament finally agreed on a double legal base. The Council and the Parliament considered that by having a double legal base, the Directive will have a balance between, on one hand, the application of the free movement rules of the Treaty, and on the other hand, the competences of the Member States in the field of healthcare services.⁹⁷

The scope of the Directive is defined in Article 1, and it appears to apply to all types of healthcare. As stated in recital 11 in the preamble to the Directive the Court has confirmed that neither its special nature, nor the way in which it is organised or

⁹⁵ Ibid p.6

⁹⁶ van de Gronden, Johan Willem ... [et al.] (2011) op. cit. n.13, p.119

⁹⁷ Matthias Wismar ... [et al.], op. cit. n.23, p. 38

financed, removes healthcare from the ambit of the fundamental principle of the freedom to provide services. The sale of medicinal products and medical devices via internet, long-term care services provided in residential homes, and the allocation of, and access to, organs for the purpose of organ transplantation are excluded from the scope of the Directive.

It should be noted that the Regulation on the coordination of social security systems has a larger material scope than the Directive. It covers all benefits in kind, including those for long-term care, which are explicitly excluded from the scope of the Directive.

Article 3(a) of the Directive defines healthcare as:

‘healthcare’ means health services provided by health professionals to patients to assess, maintain or restore their state of health, including the prescription, dispensation and provision of medicinal products and medical devices

This definition of healthcare is rather restrictive and appears to only apply to curative healthcare. That is, healthcare that is intended to improve symptoms and cure medical problems. The reason for excluding long-term care from the scope of the Directive is the complicity of the care, and the fact that the Member States provide and fund that care by different means.⁹⁸

The fourth paragraph of Article 1 expressly states that the Directive shall not affect laws and regulations in the Member States relating to the organisation and financing of healthcare in situations not related to cross-border healthcare. It is therefore clear that the Member States are intended to retain their powers to regulate in that area, and to build up and finance the national healthcare systems without intervention by the EU based on the Directive.

The persons covered by the Directive are all those insured by the national social security systems of the Member States. Thus, the persons insured are the same as those insured under the social security coordination Regulation. Reimbursement of medical expenses obtained abroad is therefore based on the person being insured in the social

⁹⁸ van de Gronden, Johan Willem ... [et al.] (2011) op. cit. n.13, p.120-122

security system of the home State (the Directive uses the words “state of affiliation” for the Member State of residence, that is, the competent Member State to grant prior authorization to an insured person. To avoid complications “home State” will be used in this dissertation). The patients that might benefit from the Directive may have different reasons to seek healthcare abroad, such as temporary visitors abroad, people retiring to other countries, people living in border regions, people sent abroad by their home systems and people going abroad on their own initiative.

4.2 The content of the Directive

The adoption of the Directive was a big step in codifying the case law of the Court of Justice in the area of healthcare services, and much needed clarity about the rights of patients who seek healthcare in another Member State has hopefully been provided. The Directive is intended to supplement the rights that patients already have at EU level through the Regulation on the coordination of social security systems 883/2004 and clarify the relationship between the Regulation and the case law of the Court. At the same time the Directive shall fully respect the case law of the Court of Justice on cross-border healthcare, as well as the right and competence of the Member States to organise their own healthcare system.⁹⁹ The Directive does not affect the right of the Member States to define the benefits made available for their citizens, and the payment for the treatment sought abroad is therefore dependent on it also being funded when provided locally. While interpreting the rules set out in the Directive it is, first of all, important to keep in mind that the Directive speaks the voice of the patients. It is the rights of the patients that the Directive is intended to clarify.¹⁰⁰

The Directive sets out, as a general principle, that patients are allowed to obtain the same care as they would be entitled to at home, in another EU Member State, and have the costs reimbursed by the home State. The reimbursement is therefore dependent on the care sought being a part of the benefits basket of the Member State where the person

⁹⁹ Summary of the final legislative act (*COD/2008/0142 of 9 March 2011*)

¹⁰⁰ Health care across borders: Implications of the EU Directive on cross border health care for the English NHS, Elisabetta Zanon, 2011, p.34.

is insured. Thus, the healthcare available to patients is based on the decision of the national authorities of the home State. The Member States are, however, allowed to limit the application of this rule based on overriding reasons of general interest, such as planning requirements or the wish to control costs and avoid waste of financial, technical and human resources.

Under specific conditions, such as with hospital and highly specialised care, the Member States may create a system of prior authorization, to limit the application of the rules of reimbursement. The Member States' restriction of the free movement of healthcare services shall, however, be limited to what is necessary and proportionate to the objective to be achieved. In chapter 5, the rule on the right to reimbursement and prior authorization will be discussed further.

While the healthcare that is sought cross-borders itself is mainly governed by the rules of the Member State where the treatment is sought, the reimbursement for the care is determined by the legislation of the Member State where the person is insured. The person seeking treatment under the conditions created by the Directive is only entitled to reimbursement up to the level that the same or similar treatment would have cost, had the treatment been provided at home. Consequently, the patient could end up paying some proportion of the expenses out of her own pocket. In the case of treatment costing less in the Member State of treatment, the level of reimbursement shall not exceed the actual amount paid for the healthcare. The patient cannot, therefore, gain any financial advantage by being treated abroad.

The Directive works side by side with the social security coordination Regulation. When a patient applies for reimbursement the reimbursement shall be made according to the more beneficial system. This will generally be the coordination Regulation, when the conditions to benefits under that Regulation are met, as it provides for reimbursement at the tariff of the State of treatment.

Finally, the Directive has some new rules that aim at promoting cooperation and mutual assistance in healthcare between the Member States. In order to improve transparency, national contact points for cross-border healthcare shall be set up. The contact points' responsibilities shall, e.g. include to provide patients with information on the available

healthcare in its territory, e.g. about price, providers and redress procedures. Providing the relevant information to patients requesting them is regarded as a key issue for enabling cross-border healthcare. The national contact points shall also facilitate the exchange of information and cooperate with each other and the Commission. The Member State of treatment shall also ensure that the relevant healthcare providers provide sufficient information to patients to help them make an informed choice on treatment. If the healthcare providers already provide patients residing in the Member State of treatment with the information, the Directive does not oblige them to provide possible cross-border patients with more extensive information.

Cooperation in eHealth and technology assessment shall also be increased, as well as the creation of a European Reference Network. The reference network shall be between the healthcare providers and centres of expertise in the Member States and have a special focus on rare diseases.

The Directive also has a provision on mutual recognition of prescriptions issued in another Member State. In principle, if a medicinal product is authorized to be marketed on the territory of a Member State, that Member State shall ensure that prescriptions issued for such a product in another Member State, by a member of a regulated health profession within the meaning of Directive 2005/36, can be dispensed on their territory in compliance with their national legislation in force. However, a pharmacist still retains the right to refuse to dispense the prescription, according to national rules or for ethical reasons, when he would also have had that right had the prescription been issued in the Member State of affiliation.

4.3 The relationship between the Directive and the social security coordination Regulation

Before looking further at the right to reimbursement under the Directive it is necessary to consider the social security coordination Regulation, and the relationship between the two.

When the Directive comes into force, the social security coordination Regulation will still remain in place. The twofold route of authorization/reimbursement for cross-border healthcare services created by the Court rulings, one based on the rules of the Regulation and the other based on case law from the Court under Article 56 of the Treaty, will still exist. The rules of the Directive will, however, replace the latter route.

In the Commission's memorandum following the proposal for the Directive¹⁰¹ the Commission defines two main reasons why patients might prefer to get healthcare abroad:

- the healthcare that they need is not available in their own system, or at least, not available within a reasonable time; or
- the healthcare is available at home, but it is more convenient for them to have it abroad because it is closer, quicker, or better.

The Commission considers those reasons different, where one is a matter of need and the other a personal preference, and finds there to be reasons to treat those groups of patients differently. If individuals need to seek healthcare abroad because the necessary care is not available domestically they should not suffer a financial loss by doing so. If, on the other hand, a person simply prefers to be treated abroad, the public funds should not have to pay the additional costs resulting from that choice. The reimbursement rules of the Directive follow this distinction by referring to the reimbursement rules of the social security coordination Regulation where relevant. The patients will, therefore, not be deprived of the more beneficial rights guaranteed under the Regulation because of the Directive.¹⁰²

In the case of emergency care, the rules of the Regulation should always be applied unless the patient specially requests otherwise. The rules of the Regulation are usually more beneficial to the patient, as the competent institutions in the relevant Member States shall make arrangements for the settlement of the costs. The patient receiving emergency care will then pay for the treatment as if he was insured in the State where the relevant treatment is given. Under the Directive the patient would generally have to

¹⁰¹ Commission staff working document, op. cit. n.86, p.28

¹⁰² See recital 31 in the preamble to the Directive

pay the whole amount up front, and later be reimbursed by the home State up to the level that the treatment would have cost if it had been provided at home. Patients in this position will, however, still benefit from the Directive as it contains requirements on providing them with information.

Reimbursement rules for planned care in another Member State, which requires authorization, do also differ between the two legal measures. The rule in Article 20 of the coordination Regulation requires the patient to seek prior authorization from the competent institution. The authorization shall be provided if appropriate treatment cannot be given at home within a medically justifiable time limit, taking into account the current state of health and the probable course of the illness. The main rule of the Directive, on the other hand, is that the patient does not need to seek prior authorization. This rule of the Directive has several exceptions that will be discussed in the following chapter. Article 8(3) of the Directive states that if an insured person request prior authorization to seek cross-border care, the authorities shall, as a first step, determine whether the conditions for the application of the social security coordination Regulations have been met. Where the conditions have been met, i.e. the treatment cannot be provided at home without undue delay, the authorization shall be granted according to the Regulation unless the patient requests otherwise.

By making it clear in the Directive that the social security Regulation shall have priority, the Directive guarantees patients the most beneficial reimbursement available. The difference in the cost of treatment in the home and host State will be paid by the patient if the authorization is provided under the rules of the Directive. Whereas, the authorization is granted under the Regulation, the difference will be covered by public funds. Reimbursement under the Regulation, therefore, ensures more financial security for the patient. The rules of the Regulation will not change following the implementation of the Directive.

5 Reimbursement under the Directive

5.1 The general rule for reimbursement

The general principle for reimbursement of medical expenses is established in Article 7 of the Directive. It states that without prejudice to Regulation 883/2004 and subject to Articles 8 and 9 the home State shall ensure that costs incurred by an insured person who receives cross-border healthcare are reimbursed. This is limited to healthcare which the insured person is entitled to under the legislation of the home State. Excluded is therefore experimental treatment abroad, such as was at issue in the cases of *Smits-Peeboms* and *Rindal and Slinning*, if there are no entitlements to such treatment in the home State. The Directive does therefore not provide for a general system of prior authorization as the social security Regulation. The Directive follows the Court rulings, where the Court has ruled that prior authorizations rules do in principle hinder the freedom to provide and receive services.¹⁰³ The main rule is, therefore, that patients are in principle free to go to another Member State and get the healthcare they need, and have the costs reimbursed by the home State, given that the treatment sought is included in the benefits basket of their home State.

The Directive therefore takes the opposite starting point to the social security Regulation. The main rule of the Regulation is that there is no entitlement to reimbursement for medical expenses obtained in another Member State, unless prior authorization has been received.

Paragraph 9 of Article 7 of the Directive provides for a general exception from reimbursement of medical expenses obtained in another Member State. The rule stipulates that the Member States may limit the application of the rules on reimbursement for cross-border healthcare based on overriding reasons of general interest. These reasons can be, for example, planning requirements relating to the aim of ensuring sufficient and permanent access to a balanced range of high-quality treatment

¹⁰³ See above in chapter 3.2

in the State concerned, or the wish to control costs and avoid, as far as possible, any waste of financial, technical and human resources. Restrictions that are based on these grounds shall not go further than what is necessary and proportionate, and may not constitute a means of arbitrary discrimination or an unjustified obstacle to the free movement of goods, persons or services. If a Member States chooses to limit reimbursement on these grounds they shall notify the Commission of such decisions.

This is an important exception from the main rule, and is a codification of principles established by the Court of Justice in several rulings that have already been discussed in chapter 3.1.1. In practice this possibility to limit the application of the main rule will likely be used by most of the Member States in order to protect the national healthcare services.

5.2 The requirement of prior authorization

The principal rule of the Directive, that medical expenses obtained in another EU Member State shall be reimbursed by the home State, can be further limited by the Member States. Article 8 of the Directive includes a special exception that allows the Member States to introduce a system of prior authorization for reimbursement of medical expenses. The requirement of prior authorization is seen by the Commission and the Court as hindering free movement of services, as was explained in chapters 3.1 and 3.2.¹⁰⁴ The Court has, however, held that restricting the reimbursement for healthcare obtained abroad can be justified on the ground of overriding reasons in the general interest, and that a prior authorization system can therefore be compatible with the Treaty. The system of prior authorization and the decision to turn down a request for prior authorization shall be restricted to what is necessary and proportionate to the objective to be achieved. It may, furthermore, not constitute a means of arbitrary discrimination or an unjustified obstacle to the free movement of patients.

¹⁰⁴ *Kohll*, op. cit. n.2, para 35, *Smits and Peerboms*, op. cit. n.16, para 61-69, *Müller-Fauré and Van Riet*, op. cit. n.17, para 44

The requirement of prior authorization is according to Article 8(2) limited to healthcare in four instances that is:

a) made subject to planning requirements relating to the object of ensuring sufficient and permanent access to a balanced range of high-quality treatment in the Member State concerned or to the wish to control costs and avoid any waste of financial, technical and human resources and;

i. the healthcare sought must involve overnight hospital stay for at least one night or

ii. require use of highly specialized and cost-intensive medical infrastructure or medical equipment.

b) Healthcare that involves treatment presenting a particular risk for the patient or the population.

c) Healthcare that is provided by a healthcare provider that, on a case by case basis, could give rise to serious and specific concerns relating to the quality or safety of the care, with the exception of healthcare which is subject to Union legislation ensuring a minimum level of safety and quality throughout the Union.

It is left to the Member States themselves to decide which categories of healthcare they will make subject to prior authorization. The categories of healthcare may therefore vary between each Member State, as the organization and delivery of healthcare is different between the Member States, and different criteria may be used for defining the healthcare where authorization is needed. The categories in point (a) that are made subject to prior authorization shall be notified to the Commission. The Member States shall make the healthcare that they make subject to prior authorization publicly available, as well as the relevant information on the prior authorization system. The Directive therefore follows closely the Court rulings on prior authorization, where the Court stated in *Smits-Peeboms*, that prior authorization could be accepted as long as it could be considered necessary and proportionate and it must be based on an objective and non-discriminatory criteria that is known in advance.¹⁰⁵

In the initial proposal for a Directive, the Commission intended to have these categories administered through a body by the Commission.¹⁰⁶ The Parliament and the Council,

¹⁰⁵ *Smits and Peeboms*, op. cit. n.16, para 75 and 90

¹⁰⁶ Commission proposal, op. cit. n.78, see Article 8(2) of the proposal, p.9

however, rejected the idea of a common definition for healthcare that may be subject to prior authorization as they considered it preferable that this would be defined by the Member States themselves.¹⁰⁷ This freedom of the Member States to decide which healthcare that needs prior authorization may lead to a broader list than was intended by the Commission. On the positive side, it is important with clarity about which healthcare that is subject to prior authorization, and what level of reimbursement a patient that intends to apply for authorization, or has received one, might be entitled to. The patient then knows what payments he might expect on his return home as well as he can organize appointments for after-treatment.

5.2.1 Hospital treatment

Like the Court has previously done in its rulings, the Directive makes a distinction between hospital care and care provided outside of a hospital, and thereby recognizes the specific nature of hospital services.¹⁰⁸ As provided for in Article 8(2), healthcare that is made subject to planning and involves overnight hospital accommodation for at least one night may be subject to prior authorization. The Article thereby sets out in a clear way what constitutes hospital care as it depends on the overnight stay. Thus, if a person seeks healthcare in another Member State and attends a follow up on the following day after spending the night at a hotel or with relatives, it is not considered hospital care as the night is not spent at the hospital.

Prior to the Directive there has been no consistent definition in the different health systems in the EU of what constitutes hospital care. This definition therefore provides for a minimum harmonization between the various healthcare systems, and therefore gives more clarity to the patients considering healthcare abroad.¹⁰⁹

¹⁰⁷ European Parliament Report, op. cit. n.89, amendment 75. See also Council position at first reading with a view to the adoption of a Directive on the application of patients' rights in cross border healthcare *11038/10 of 3 September 2010*, see Article 7(10)

¹⁰⁸ See for example *Smits and Peerboms*, op. cit. n.16, para 76-80, where the Court considered the requirement of prior authorization justified when concerning medical services provided within a hospital

¹⁰⁹ Commission proposal, op. cit. n.78, p.15

The Member States may justify the prior authorization system for hospital care by the need to plan the number of hospitals, their geographic distribution, the mode of their organization and the equipment with which they are provided. Such planning seeks to achieve the aim of ensuring sufficient and permanent access to a balance range of high-quality hospital treatment in the State concerned. It also assists in meeting a desire to control costs and to prevent, as far as possible, any wastage of financial, technical and human resources.¹¹⁰ Requiring prior authorization for hospital care therefore appears to be a measure that is both necessary and reasonable.¹¹¹

If a Member State chooses to use this possibility to limit the reimbursement for hospital treatment provided in another Member State, the rule does not require the national authorities to demonstrate how this limitation is necessary to prevent distortion of the national system. It remains to be seen how this will work in practice and the Member State should, when making hospital care subject to prior authorization, use the previous rulings of the Court of Justice as an advice.

5.2.2 Highly specialized treatment

The Directive also allows the Member States to make subject to prior authorization healthcare that is not provided in a hospital, but is made subject to planning requirements and “requires use of highly specialized and cost-intensive medical infrastructure or medical equipment”. It is not clear what equipment or infrastructure the Directive is referring to, and one must therefore rely on previous interpretations by the Court.

In paragraphs 40 and 41 in the preamble to the Directive it is stated that it is for each Member State to decide whether a treatment is subject to prior authorization. Whether or not prior authorization for the treatment will be permitted will vary and will depend on the type of equipment. Whether the healthcare is delivered in or out of hospital environment is not the decisive factor for deciding whether it requires planning or not.

¹¹⁰ Recital 40 in the preamble to the Directive

¹¹¹ *Smits and Peerboms*, op. cit. n.16, para 76-80

As Advocate General Sharpston suggested in her Opinion¹¹² in the case *Commission v France*, there are several factors to take into consideration when evaluating the legitimacy of a national rule requiring prior authorization for treatment that is highly specialized or cost-intensive. First, whether the capital cost of the equipment in question is high, and if the cost is likely to be very considerable and require a substantial investment by the competent authorities. Secondly, the operating costs may be sufficiently significant to require separate provision within the relevant budget. Third, the equipment in question will probably be specialist equipment, in the sense of the equipment that is dedicated to a particular medical procedure or type of analysis. Fourth, it is likely to be equipment that is used only after the patient has been through some kind of preliminary screening process, rather than equipment that is used routinely for first stage diagnosis and/or treatment. Fifth, the equipment may well require suitably-trained staff to install, maintain and operate it.

This point is open for interpretations by the Member States, and each Member State might interpret it differently. Future disputes before the Courts regarding the understanding of this point are therefore expected, as the Member States might be inclined to conclude “a bit too easily”¹¹³ that a specific treatment needs expensive equipment that will need planning, and therefore consider the requirement of the Directive, to require prior authorization, fulfilled.

5.2.3 Particular risk for the patient or for the population

If the healthcare involves treatments presenting a particular risk for the patient or the population it may be made subject to prior authorization. This rule must be considered to exist in order for the authorities to protect the citizens against specific concerns.

One can imagine patients wishing to travel with highly infectious diseases for example, or patients that have highly unstable conditions that might not allow them to safely make long distance journeys. The authorization might also, possibly, be turned down on

¹¹² Opinion of A.G. Sharpston in the case *Commission v France*, op. cit. n.66, para 79

¹¹³ van der Mei, Anne Pieter, *Case C-512/08, Commission v. France, Judgment of the European Court of Justice (Grand Chamber) of 5 October 2010*; *Case C-173/09, Georgi Ivanov Elchinov v. Natsionalna zdravnoosiguritelna kasa, Judgment of the Court of Justice (Grand Chamber) of 5 October 2010* (2011), 48 Common Market Law Review, p. 1297–1311, p.1303

the grounds that the patient is wishing to travel to a Member State at a time when an infectious disease is occurring there.

5.2.4 Concerns about the healthcare provider

Healthcare may be subject to prior authorization if it is provided by a healthcare provider that could give rise to serious and specific concerns relating to the quality or safety of the care. This does not, however, apply to healthcare which is subject to Union legislation ensuring a minimum level of safety and quality throughout the union.

The Court stated in its ruling in *Kohll*, that the Luxembourg authorities could not argue that the prior authorization was necessary in order to ensure the safety and quality of the treatment, as the activities of health professionals had been subject to EU harmonization Directives.¹¹⁴ For this reason it is not clear when this point could be used to require prior authorization. See further chapter 5.3 below on Article 8(6)(c).

5.3 Reasons to refuse to provide prior authorization and the concept of “undue delay”

The Member States have limited reasons to refuse to grant prior authorization, following the exhaustive list in Article 8(6) of the Directive. As the social security Regulation did not include any rules on when authorization could be refused, these rules are new. The list is limited, which is perhaps appropriate given the broad scope of healthcare that may be subject to prior authorization and that the Member States already have the right to limit the reimbursement based on overriding reasons of general interest, as discussed above in chapter 5.1.

According to point (a) of paragraph 6, application for authorization to seek cross-border healthcare may be refused, if a clinical evaluation of the treatment has been made, and that evaluation indicates, that the patient will with reasonable certainty be exposed to a

¹¹⁴ Op. cit. n.45

patient-safety risk. This risk must be deemed not acceptable, taking into account the potential benefit the patient might gain from the treatment.

Following point (b) the authorization may furthermore be refused, if the cross-border healthcare will, with reasonable certainty, result in exposing the general public to a substantial safety hazard.

Point (c) relates to chapter 5.2.4 above, and states that the authorization can be turned down if the healthcare is to be provided by a healthcare provider that raises specific concerns that relate to the quality of care and patient safety. As stated in chapter 5.2.4, it is not clear when the Member States can use this reason to refuse to provide prior authorization. It must be assumed, however, that the Member State raising this justification has concrete concerns relating to the compliance with the applicable quality and safety standards of the care in the EU.

Point (d) states that the prior authorization can be refused if the healthcare can be provided on the territory of the home State within a time limit which is medically justifiable. The authorities must take into account the patients current state of health and the probable course of the illness. This reason to refuse prior authorization is likely to be much used by the national authorities.

The Member States cannot, however, refuse to grant prior authorization when the healthcare cannot be provided by a nationally based provider within undue delay. This rule is set out in further detail in paragraph 5 of Article 8.

The concept of “undue delay” has been the subject of many rulings from the Court of justice. Although the Member States are free, within the limits laid down in Article 8 of the Directive, to define the scope of healthcare that requires authorization, the Court has repeatedly ruled that authorization cannot be refused when the patient is entitled to the healthcare in question in accordance with national law, and the healthcare cannot be obtained at home within medically justifiable time limits.¹¹⁵ In paragraph 5 of Article 8 it is stated, that the Member States cannot refuse to grant prior authorization when healthcare cannot be provided within a time limit which is medically justifiable. It

¹¹⁵ *Smits and Peerboms*, op. cit. n.16, para 103, *Watts*, op. cit. n.16, para 37-38

further states, that when evaluating the need for a treatment, the competent institution is required to base the decision on an objective medical assessment of the patients' medical condition, the history and probable course of the patients' illness, the degree of the patients' pain and/or the nature of the patients' disability at the time when the request for authorization was made.

The description of "undue delay" in the Directive is more detailed than it is set out in Article 20(2) of the coordination Regulation. There it is merely stated that authorization shall be given where the treatment in question is among the benefits provided for by the legislation in the Member State where the person concerned resides, and where the treatment cannot be given within a time limit which is medically justifiable taking into account the patients current state of health and probable course of the illness.

The national authorities are entitled to use waiting lists to manage available hospital capacity and to prioritize in their territory. The Court has, however, made clear that the existence of waiting lists for hospital treatment in itself does not justify a refusal to provide authorization to seek necessary treatment abroad. The competent institution to grant prior authorization is required to take into account all circumstances of the individual case and the clinical needs of the person.¹¹⁶

In the case of *Müller-Faure* the Court found that when determining whether treatment which is equally effective can be obtained without undue delay, all circumstances of each specific case shall be considered. Account shall be taken of the patients' medical condition at the time when authorization is sought and medical history. Furthermore, the degree of pain shall be considered or the nature of the disability which might, for example, make it impossible or extremely difficult for him to carry out a professional activity.¹¹⁷

To conclude, when the patient is entitled to healthcare at home that cannot be provided within a medically justifiable time limit, the State is in principle obliged to grant prior authorization. In certain circumstances defined in Article 8(6), cross-border healthcare may expose the patient or the general public to a risk which overrides the interest of the

¹¹⁶ *Müller-Fauré and Van Riet*, op. cit. n.17, para 92, *Watts*, op. cit. n.16, para 75

¹¹⁷ *Müller-Fauré and Van Riet*, op. cit. n.17, para 90

patient to receive the cross-border healthcare sought. The granting of prior authorization can also be restricted based on concerns relating to the healthcare provider. In such instances, the home State should have the opportunity to refuse the request for prior authorization, and direct the patient towards alternative solutions.

5.4 Summarizing the rule on the right to reimbursement

The Directive sets out the main rule that patients are in principle free to get the medical care they are entitled to at home in another EU State, and get the costs reimbursed by their home State. There are, however, many exceptions to this rule, which in effect significantly impedes the main rule.

The general exception from this rule is that the reimbursement can be limited based on overriding reasons of general interest. This is a broad restriction on the free movement of services, which is based on the Court rulings in several cases where the Court has found such measures to be both necessary and proportionate. Furthermore, the Member States may limit the application of the rules on reimbursement even further by introducing a system of prior authorization. The prior authorization may be refused if the treatment can be provided at home within a medically justifiable time limit, but may, however, not be refused if it cannot be provided at home without undue delay for the patient. However, if the reasons listed in the exhaustive list in Article 8(6) (a) – (c) are applicable, they may in turn override the obligation of the Member States to provide treatment without undue delay.

It is most likely that all the Member States will use the opportunity and limit the right to seek healthcare cross borders based on the reasons of general interest. It must also be considered likely that they will introduce a system of prior authorization. The system will vary between each Member State, as the States organize their healthcare systems differently, as well as having different financial means.

Following the Directive reimbursement is only made up to the level that the treatment would have cost had it been provided in the home State. This has, however, been criticized in the light of the principle of equal treatment and the free movement of

persons. As the patient has to pay the difference between the actual cost of treatment and the reimbursement received, patient mobility can be restricted. The Directive will therefore likely primarily be used to seek reimbursement for treatment abroad that is provided at similar or lower costs as in the patients' home State.¹¹⁸

5.5 Administrative procedures

The administrative procedures regarding cross-border healthcare are mostly laid down in Articles 7 and 9 of the Directive. The procedures will not all be listed here, but those relevant for the topic of this dissertation will be addressed.

The Member States shall set out reasonable time limits to deal with requests for cross-border healthcare and make them public in advance. In the initial proposal the Commission considered a period of fifteen calendar days considered normal, and this could be shorter if urgency requires.¹¹⁹ The administrative procedures shall be based on objective, non-discriminatory criteria and the criteria shall be necessary and proportionate to the objective to be achieved. When the competent authorities in the Member States are considering a request for cross-border healthcare, they shall take into account (i) the patient's specific medical condition and (ii) the urgency and other individual circumstances. The decisions following a request for cross-border healthcare shall be properly reasoned and be subject to judicial review.

As previously mentioned, after receiving a request for prior authorization to seek treatment abroad, the first step is to determine whether the conditions laid down in Regulation 883/2004 have been met. Where those conditions are met, the prior authorization shall be granted according to the Regulation unless the patient requests otherwise.

When a patient is seeking reimbursement for cross-border healthcare, the home State may, according to Article 7(7), impose on the person the same requirements as it would if the treatment had been provided at home. This has been referred to as the "gate-

¹¹⁸ van de Gronden, Johan Willem ... [et al.] (2011) op. cit. n.13, p.157

¹¹⁹ Commission proposal, op. cit. n.78, p.28

keeping-principle”. This can consist of an assessment by a health professional or healthcare administrator providing services for the health system of the State where the person is insured. This may e.g. include an obligation to consult a general practitioner before consulting a specialist, or before receiving hospital treatment.

As the State where the healthcare is given treats the patient according to its own legislation this must be considered to apply also to the State of treatment. The Member States can therefore set this as a condition for accepting patients from other EU States. The Member States may only require this if necessary for determining the individual patient’s entitlements to healthcare. Patients seeking cross-border healthcare may not be subject to any additional conditions that do not apply when the treatment is provided by a nationally based provider.

The competent institution of the home State shall reimburse the costs to the patient, or directly to the institution in the place where the treatment was given. The amount shall be made up to the level of the costs that the same or similar healthcare would have cost had it been provided at home and shall not exceed the actual cost of the healthcare received. The Member State may decide to reimburse other related costs, such as accommodation and travel costs, or extra costs which persons with disabilities might incur due to one or more disabilities when receiving cross-border healthcare. These costs will be reimbursed in accordance with national legislation and on the condition that there is sufficient documentation setting out the costs.

The Member States shall, according to Article 7(6), set up a transparent mechanism for cost calculation. The mechanism shall be based on objective, non-discriminatory criteria known in advance and applied at the relevant administrative level. This obligation may be related to the problem in the *Watts* case, where the Court had to rule on how to determine the reimbursement rate to Ms Watts. The Court of justice has developed an approach based on the presumption that the patient must be placed in the position he would have been in had he undergone the operation at home. As the British NHS system, where Ms Watts was insured, provided the treatment free of charge, the State was forced to carry out a comparative analysis of the costs to determine on the

amount of reimbursement.¹²⁰ This mechanism has also been criticized as it will be a complicated work for the Member States to define the costs for treatments and, secondly, the rule does not set out a measure that harmonizes the methodology used by the Member States for the cost calculation.¹²¹

¹²⁰ Van De Gronden, Johan W, *Cross-Border Health Care in the EU and the Organization of the National Health Care Systems of the Member States: The Dynamics Resulting from the European Court of Justice's Decisions on Free Movement and Competition Law*, Wisconsin International Law Journal, No 26, 2008-2009, p.720

¹²¹ van de Gronden, Johan Willem ... [et al.] (2011) op. cit. n.13, p.201-202

6 Conclusion

Having assessed the Court rulings regarding cross-border healthcare from *Kohll* and *Decker* and until today, it is clear that the involvement of the EU was necessary as the right to seek treatment cross-borders has been unclear. The Directive follows closely the case law from the Court, and sets out clarification on the rights of individuals to get the costs for cross-border healthcare reimbursed. Having assessed the rules of the Directive, especially Articles 7 and 8, one can however ask whether the objective of the Directive, to provide legal clarity and certainty, really has been achieved, as the exceptions to reimbursement are quite cumbersome?

The Directive sets out the principal rule discussed in chapter 5.1 above, that patients are free to seek healthcare in another EU Member State and get the costs reimbursed by the home state. It is, however, only the cost of healthcare that the patients already have right to under their national healthcare system that is to be reimbursed. The Member States may, furthermore, limit this freedom based on overriding reasons of general interest, such as planning requirements relating to the aim of ensuring sufficient and permanent access to a balanced range of high-quality treatment in the State concerned, or the wish to control costs and avoid, as far as possible, any waste of financial, technical and human resources. Article 8 allows for further limitation by giving the Member States the opportunity to introduce a system of prior authorization.

The rules of the social security Regulation will still remain in place. The authorization procedure in the Regulation is different to that of the Directive. The fact that the two legal tools do not have completely identical procedures can make it more difficult for insured persons to understand their rights to seek healthcare in another EU State.

With those two legal tools working side by side the parallel route to reimbursement created by the Court rulings on Article 56 continues to remain. When the conditions for reimbursement under the social security Regulation are met, the reimbursement shall be made under that Regulation. Under the Regulation the patient pays for the healthcare

received abroad as if he was insured under that system, while the home State reimburses the cost to the institution in the place where he was treated. Under the Directive, on the other hand, the patient pays the full amount for the treatment, and is then entitled to be reimbursed by the home State up to the amount that the treatment would have cost had it been provided at by a nationally based provider.

To enhance clarity and avoid complications between the Directive and the Regulation, including the principles of the Court's rulings in the social security Regulation, instead of giving a new Directive, could have been a better way forward.

Following the adoption of the Directive, some have worried that the EU is reaching too far by regulating the healthcare market and that the sovereignty of the national healthcare systems is at risk. The Directive does, however, clearly state that it is not intended to affect the national organization of healthcare services and it appears as the Directive will not increase the right to treatment in any way.

To conclude, it is safe to say that the Directive has given some clarification and practical effect to the rights that the Court recognized in its rulings. The right to seek healthcare in another Member State, and have the costs reimbursed from the home State, is a right that many EU nationals have not been aware of. The entering into force of the Directive is likely to increase awareness of the possibility to seek healthcare abroad and get the costs reimbursed. More EU nationals are therefore likely to use their right to seek healthcare cross borders in the coming years.

7 Table of references

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